

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA

CRIMINAL NO. 3:10-CR-301

v.

BENNY SALERNO,

Defendant.

FILED
SCRANTON

OCT 19 2010

~~PER~~ *AS* ~~DEPUTY CLERK~~

I N D I C T M E N T

INTRODUCTION

1. The Pennsylvania Pharmacy Board oversees the practice of pharmacy throughout the Commonwealth of Pennsylvania. All pharmacists and pharmacies are regulated by the Pennsylvania Pharmacy Act (Act 669 of 1961) ("Pennsylvania Pharmacy Act") and by all other applicable state and federal regulations. Pennsylvania Law prohibits the return medication to stock once it has left the premises of any pharmacy. Specifically, the Pennsylvania Pharmacy Act precludes the acceptance back and redistribution of any unused drug, or part thereof, after it has left the premises of the pharmacy, whether issued by mistake or, otherwise, unless it is in the original sealed container with the name, lot number, and expiration date on the original intact manufacturer's label. Drugs dispensed in blister packs, prepared by the pharmacy, can never be

accepted back for redistribution after they have left the pharmacy pursuant to the Pennsylvania Pharmacy Act, Section 5(9)(xi).

2. The Pennsylvania Medicaid Program is a "healthcare benefit program" as defined by Title 18 U.S.C. § 24 in that it provides payment for health care services on behalf of eligible low-income individuals with limited income and high medical expenses.

3. The Pennsylvania Medicaid Program is jointly funded by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services and the Commonwealth of Pennsylvania.

4. The United States Food and Drug Administration ("FDA") is the agency of the United States responsible for enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et. seq., and assuring that drugs sold to humans are safe and effective and bear true and accurate labeling. FDA's responsibilities include regulating the labels, labeling, distribution, and manufacture of prescription drugs shipped or received in interstate commerce.

5. It is a prohibited act under the FDCA to do any act that causes a drug to become misbranded after it has moved in interstate commerce and while it is held for sale (whether or not the first sale). 21 U.S.C. § 331(k). A drug will be deemed misbranded, among other things, if its labeling is false or misleading in any particular manner. 21 U.S.C. § 352(a). A drug will also be deemed misbranded if its labeling does not bear information required by or under authority of the FDCA. 21 U.S.C. § 352(c). By regulation, FDA requires that drug products bear an expiration date determined by appropriate stability testing to "assure that [it] meets applicable standards of identity, strength, quality, and purity at the time of use." 21 C.F.R. § 211.137. The expiration date must appear on the outer container. 21 C.F.R. § 201.17. Drug labels are also required to bear a lot number capable of yielding the complete manufacturing history of the package. 21 C.F.R. § 201.18.

6. Salerno's Pharmacy was owned and operated by BENNY SALERNO. The business operated as a "closed pharmacy", located at Sciota, Monroe County, Pennsylvania. A "closed pharmacy" does not operate as a retail pharmacy that

provides prescription medications to the general public, and, instead, only provides prescription medications to institutions such as hospitals, personal care homes, nursing homes and other residential medical facilities.

7. The vast majority of prescription drugs dispensed by Salerno's pharmacy were taken from manufacturer stock bottles, placed into blister pack cards and sealed and labeled with the patients' names, type of medication and any other information required under state and federal law. Blister packs are cards with pre-formed holders for each individual pill. Once the blister packs were filled, sealed and labeled, the prescription drugs were delivered by pharmacy employees to the various health care institutions where patients resided. Medicaid and other third party payors were then billed by Salerno's Pharmacy for those drugs. Frequently, the healthcare institutions returned unused portions of the prescription drugs to Salerno's Pharmacy delivery persons during the scheduled deliveries of newly dispensed drugs.

8. The Pennsylvania Pharmacy Act prohibits the redistribution or re-dispensing of the returned pharmaceuticals.

THE SCHEME TO DEFRAUD

The scheme to defraud was carried out by Benny Salerno in the following manner:

9. The defendant was the owner and on-site manager of Salerno's Pharmacy. As such, Salerno was present at the pharmacy on a daily basis and was responsible for the management of the pharmacy. Salerno maintained closed circuit surveillance of the pharmacy operations by a large screen television which was wired to multiple cameras throughout the facility, including the pharmacy floor where the process of removing and returning unused portions of pills to stock bottles occurred.

10. As the owner and manager of operations, Salerno directed employees to retrieve the unused portions of blister packs from various medical facilities and return the unused portions to Salerno's Pharmacy.

11. Contrary to the mandates of the Pennsylvania Pharmacy Act, Salerno directed employees to remove the unused pills from the previously dispensed and returned blister packs and return the pills to manufacturer stock bottles, thereby co-mingling returned pills with those pills contained within the stock bottles.

12. The manner in which the pills were returned to stock, without regard to the manufacturer's lot number and/or expiration date resulted in the misbranding of the entire portion of drugs contained in the stock bottle.

13. Specifically, Salerno directed pharmacy technicians to remove the individual pills from the blister packs and place them into containers, usually plastic or paper cups, in front of the stock bottles of the type and brand of pharmaceutical that the technician believed the pharmaceutical to be. A pharmacist would review the medications to determine whether the pills in the cups were the same type of pills on the label of the stock bottle and then pour the returned pills back into stock bottles which were used to fill future prescriptions.

14. The misbranded Pharmacy stock was then used to fill prescriptions and dispensed to healthcare institutions. Salerno's pharmacy then billed Medicaid and other third party payors for the misbranded prescriptions.

15. In doing so, Salerno fraudulently claimed payment for dispensed pharmaceuticals that were misbranded within the meaning of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §331(k). These pharmaceuticals were also dispensed in violation of the Pennsylvania Pharmacy Act.

COUNT 1

FALSE STATEMENTS RELATING TO HEALTH CARE MATTERS

(18 U.S.C. §1035)

16. The allegations contained in paragraphs 1 through 15 of this Indictment are alleged and incorporated as if fully stated herein.

17. On or about, January 1, 2001 through March 1, 2006, in the Middle District of Pennsylvania and elsewhere, the defendant,

BENNY SALERNO

did, in a matter involving a health care benefit program, knowingly and willfully falsify, conceal, and cover up by any trick, scheme, or device a material fact, to wit: the defendant, as the owner and manager of Salerno's Pharmacy, caused the submission of claims for payment from the Pennsylvania Medicaid Program for prescription medications that he knew or had reason to know were both "misbranded" pursuant to the Federal Food Drug and Cosmetic Act and dispensed in violation of the Pennsylvania Pharmacy Act.

In violation of Title 18, United States Code, §1035 and Section 2.

COUNT 2

HEALTH CARE FRAUD

(18 U.S.C. §1347)

18. The allegations contained in paragraphs 1 through 17 of this Indictment are alleged and incorporated as if fully stated herein.

19. On or about, January 1, 2001 through March 1, 2006, in the Middle District of Pennsylvania and elsewhere, the defendant,

BENNY SALERNO

did knowingly and willfully execute and attempt to execute the above-described scheme and artifice to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by and under the custody and control of Pennsylvania Medicaid Program, a health care benefit program as defined in Title 18, United States Code, Section 24(b), in connection with the payment for health care benefits, items, and services, to wit: the defendant caused to be submitted claims for payment of dispensed pharmaceuticals knowing or having reason to know that the pharmaceuticals were both "misbranded" pursuant to the Federal Food Drug and Cosmetic Act and dispensed in violation of the Pennsylvania Pharmacy Act.

In violation of Title 18, United States Code, Section 1347.

Count 3

CAUSING DRUGS TO BECOME MISBRANDED

(21 U.S.C. § 331(k))

20. The allegations contained in paragraphs 1 through 19 of this Indictment are alleged and incorporated as if fully stated herein.

21. On or about, January 1, 2001 through March 1, 2006, in the Middle District of Pennsylvania and elsewhere, the defendant,

BENNY SALERNO

with the intent to defraud and mislead, did acts that caused drugs to become misbranded while they were held for sale (whether or not the first sale) after shipment in interstate commerce, to wit: the defendant directed that previously dispensed but unused drugs that had been returned from hospitals, nursing homes and other health care institutions be co-mingled in manufacturer stock bottles with drugs that had never been dispensed, thereby causing the stock bottles to bear false and misleading labeling in that the lot number and expiration dates required by law to appear on the label did not accurately reflect the lots and expiration dates of all the drugs contained within the stock bottle.

In violation of Title 21, United States Code, §§ 331(k), 352(a), 333(a)(2).

FORFEITURE ALLEGATION

22. The allegations contained in Count 2 of this Indictment are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 18, United States Code, Section 982(a)(7).

23. Upon conviction of the offense in violation of Title 18, United States Code, Section 1347 set forth in Count 2 of this Indictment, the defendant, Benny Salerno, shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense. The property to be forfeited includes, but is not limited to, the following:

United States currency in the amount of \$12,689,179.55 and all interest and proceeds traceable thereto, in that such sum in the aggregate is property which was involved in the aforeslated offenses and is traceable to such property in violation of Title 18, United States Code, Section 1347.

24. If any of the property described above, as a result of any act or omission of the defendant:

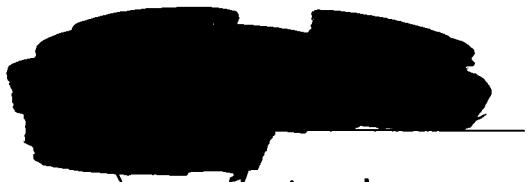
- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty;

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1) and Title 28, United States Code, Section 2461(c).

All pursuant to 18 U.S.C. § 982(a)(7) and 28 U.S.C. § 2461(c).

A TRUE BILL

Peter J. Smith acp
PETER J. SMITH
United States Attorney


Dated: 10/19/2010